

REMARKS

Prior to entry of the present amendment, Claims 23-29, 34, and 39 were pending in the application, claims 1-22, 30-33, 35-38, and 40-42 having been withdrawn from consideration under a restriction requirement. Claims 23-29 and 39 have been amended. Claim 34 has been canceled. No new matter has been added. Claims 23-29 and 39 are pending after entry of the present amendment.

INTERVIEW SUMMARY

Applicants and their Attorneys thank the Examiner for her time and consideration during the personal interview on Tuesday, April 1, 2008 at the U.S. Patent and Trademark Office. The interview is summarized herein by way of the foregoing claim amendments and the following remarks, in accordance with MPEP § 713.04.

In the interview, Applicants exhibited samples of an exemplary embodiment of an anisotropic wound packing as recited in the claimed medical device for treating a wound, and demonstrated that the wound packing has at least one predetermined direction of preferential contraction in response to suction. The Examiner agreed, as recorded in the Interview Summary, that the dressing of U.S. Patent No. 4,969,880 (Zamierowski) is not anisotropic and that it would not be obvious to modify the dressing of Zamierowski to meet the claimed invention. The Examiner further agreed, that Zamierowski, alone or in combination with U.S. Patent No. 5,447,505 (Valentine), does not anticipate or render obvious claims 23 and 39, the independent claims pending in the application.

The pending claims 23-29 and 39 are identical to those discussed with the Examiner in the interview of April 1, 2008.

SUPPORT FOR CLAIM AMENDMENTS

Claim 23 has been amended to recite “an enclosure” instead of “sealing means” and to recite “an anisotropic wound packing” instead of “wound packing means [that is] anisotropic.” Support for these amendments can be found at least at paragraphs [0025] to [0026] and paragraphs [0045] to [0047], respectively.

Claim 24 has been amended to conform with claim 23, from which it depends.

Claim 25 has been amended to conform with claim 24, from which it depends, as well as to more clearly recite the claimed invention.

Claim 26 has been amended to conform with claim 25, from which it depends.

Claim 27 has been amended to conform with claim 24, from which it depends, as well as to more clearly recite the claimed invention.

Claim 28 has been amended to delete the dependency from withdrawn claim and to more clearly recite the claimed invention.

Claim 29 has been amended to recite "a spring element" instead of "spring means." Support for this amendment can be found at least at paragraph [0036] and in FIGS. 1, 2, 4.

Claim 39 has been amended to recite a "wound packing" instead of "wound packing means" and has been further amended to recite that the predetermined orientation "preferentially allows a controlled strain to be imposed on the wound tissue in a medically preferred direction." Support for this amendment can be found at least at paragraph [0046]. Also, the preamble of claim 39 has been placed in proper independent form.

OATH / DECLARATION

The Office Action indicated that the originally filed declaration was defective. A new declaration in compliance with 37 C.F.R. § 1.67(a) is filed herewith. Accordingly, Applicants respectfully request withdrawal of the objection to the declaration.

CLAIM REJECTIONS

35 U.S.C. § 102 Rejection (Zamierowski)

Claims 23, 24, 28, and 34 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,969,880 (Zamierowski). Claim 34 has been canceled.

It is hornbook law that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d

1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added)).

Claim 23

Zamierowski does not disclose, expressly or inherently, each and every element recited in claim 23. In particular, Zamierowski does not disclose “an anisotropic wound packing . . . having at least one predetermined direction of preferential contraction in response to suction,” as recited in as-amended claim 23. (Applicants note that this claim element is no longer recited in means-plus-function form.)

The term “anisotropic” is defined as “exhibiting properties with different values when measured in different directions.” Merriam-Webster Online Dictionary, <http://www.m-w.com/dictionary/anisotropic>. This definition comports with Applicants’ recitation of the claimed anisotropic wound packing having at least one predetermined direction of preferential contraction in response to suction, i.e., when suction is applied, the claimed wound packing contracts differently in at least one predetermined direction as compared with other directions.

Zamierowski does not disclose such a wound packing. Rather, Zamierowski teaches only that a material layer 250 can be placed over the wound site (Zamierowski at col. 8, lines 30-31), the material layer comprising a mesh or sheet of synthetic material such as rayon, “Envinet,” polyurethane foam, and polyurethane mesh (Zamierowski at col. 8, lines 3-10, 25-27). Nothing in Zamierowski or in the background art would indicate to one of ordinary skill that any of these materials exhibits at least one predetermined direction of preferential contraction in response to suction.

In sum, Zamierowski does not disclose each and every element recited in claim 23. Moreover, a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on Zamierowski, alone or in combination with any other disclosure, teaching, or suggestion in the prior art. See MPEP § 2141.

Accordingly, claim 23 is novel over Zamierowski, and per the Interview Summary of April 1, 2008, claim 23 is also nonobvious over Zamierowski.

Claim 24

As-amended claim 24 recites that the packing comprises gauze. The Office Action contends that the Envinet mesh disclosed by Zamierowski is the same as gauze, although there is no indication in the reference or from any other citation that this is the case. Indeed, Applicants respectfully submit that Envinet is not gauze, otherwise Zamierowski would have simply taught gauze instead of teaching the use of a specific brand of synthetic material.

To the best of Applicants' knowledge, Envinet, which is no longer on the market, comprises a nylon material. Zamierowski describes Envinet mesh as a "surface active" material that promotes fibrin sealing on the wound surface and wicks fluid from the wound. Zamierowski at col. 8, lines 8-16. Zamierowski then compares Envinet to "Owens rayon," and notes that polyurethane foam and polyurethane mesh could also be used. Zamierowski at col. 8, lines 18-27. If Zamierowski had contemplated the use of gauze, which is widely used in wound treatment, Zamierowski would have mentioned gauze. This omission is strong evidence that Zamierowski did not believe that gauze would perform as required if used as the intermediate material layer 250.

In sum, Zamierowski does not disclose each and every element recited in claim 24. Moreover, a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on Zamierowski, alone or in combination with any other disclosure, teaching, or suggestion in the prior art.

Accordingly, claim 24 is novel over Zamierowski, and per the Interview Summary of April 1, 2008, claim 24 is also nonobvious over Zamierowski. Additionally, claim 24 depends from claim 23, and is patentable for at least the same reasons as claim 23.

Claim 28

As-amended claim 28 recites an inlet conduit connecting the bulb to the enclosure and an outlet conduit connecting the bulb to discharge. Zamierowski does not disclose these features.

The Office Action asserts that the tube 41 is an inlet to the vacuum source 42 but that the tube 34 is an outlet from the vacuum source 42, because medication can be pumped into

the wound via the tube 34. But because the tube 34 can serve as an inlet tube to the wound does not mean that it serves as an outlet to the vacuum source 42.

As disclosed in Zamierowski, the tube 34 and the tube 41 are not an inlet and an outlet, respectively, with respect to the vacuum source 42. Rather, the tubes 34 and 41 operate in series as the same conduit connecting the vacuum source 42 to the wound. Zamierowski at Fig. 6. For use as an inlet to the vacuum source 42, the tube 42 is inserted into the distal end 38 of the tube 34, and the tubes 34 and 41 are interconnected by ties 43. Thus, the series combination of tube 34 and tube 41 is an inlet conduit, and only an inlet conduit, to the vacuum source 42. Zamierowski at col. 4, lines 38-43, Fig. 6.

Nowhere does Zamierowski disclose an outlet from the vacuum source 42. Further, because the tubes 34 and 41 form only an inlet conduit to the vacuum source 42 from the wound, and the vacuum source 42 cannot pump fluid into the wound. In contrast, the claim recites both an inlet conduit connecting the bulb to the enclosure engaging the skin around the wound and an outlet conduit connecting the bulb to discharge.

In sum, Zamierowski does not disclose each and every element recited in claim 28. Moreover, a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on Zamierowski, alone or in combination with any other disclosure, teaching, or suggestion in the prior art.

Accordingly, claim 28 is novel over Zamierowski, and per the Interview Summary of April 1, 2008, claim 28 is also nonobvious over Zamierowski. Additionally, claim 28 depends from claim 23, and is patentable for at least the same reasons as claim 23.

Accordingly, for at least the foregoing reasons, Applicants respectfully request that the anticipation rejections of claims 23, 24, and 28 over Zamierowski be withdrawn.

35 U.S.C. § 103 Rejection (Zamierowski in view of Valentine)

Claims 25-27 and 39 stand rejected under 35 U.S.C. § 103 as being obvious under Zamierowski in view of U.S. Patent No. 5,447,505 (Valentine).

In making a case for obviousness under § 103, the Examiner must: (1) determine the scope and content of the prior art; (2) ascertain the differences between the prior art and the claims at issue; (3) resolve the level of ordinary skill in the pertinent art; and (4) evaluate evidence of secondary considerations. *Graham v. John Deere*, 383 U.S. 1 (1960); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

When applying § 103, the following tenets of patent law must be followed: (1) the claimed invention must be considered as a whole; (2) the references must be considered as a whole; (3) the references must be viewed without the benefit of impermissible hindsight afforded by the claimed invention; and (4) the standard for determining obviousness is a reasonable expectation of success. MPEP § 2141.

Claim 25

The Office Action contends that it would have been obvious to modify the article of Zamierowski based on the teachings of Valentine to obtain the claimed invention. Applicants respectfully submit that this assertion is refuted by the disclosures of both Zamierowski and Valentine, as well as by the present application.

First, as discussed above with regard to claim 24, Zamierowski does not teach gauze. Moreover, Valentine specifically teaches away from the use of gauze in a wound dressing. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.03(VI) (citing *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). In particular, Valentine explains that prior art systems using a combination of film dressings and gauze dressing suffer from "all the limitations and disadvantages of using films and gauze." Valentine at col. 6, lines 25-34. Thus, Valentine teaches the use of a polyvinyl acetal sponge (i.e., foam), instead of gauze or film or other prior dressings. Valentine at col. 6, lines 40-42.

Valentine touts the dressing disclosed therein as having properties that render it superior to gauze for the intended use. As proof, Valentine sets forth a detailed comparison between the inventive dressing, gauze, and several other materials in Table 1. Valentine at col. 8, lines 17-18. (Applicants note that Valentine Table 1 is missing the header text which identifies each of the dressing materials. However, a complete table having the correct header

is included in the Table 1, on page 16, of the International Publication WO95/04510 of PCT Application No. PCT/US94/08493, which claims priority to U.S. Application No. 08/101,686 from which the U.S. Patent 5,447,505 (Valentine) issued. Table 1 in WO95/04510 is otherwise identical to Table 1 in the '505 patent. Accordingly, Applicants respectfully submit that it is appropriate to rely on Table 1 in WO95/04510 to supply the header information missing from Table 1 in the '505 patent. For the Examiner's convenience, Table 1 from WO95/04510 is inserted below.)

TABLE I							
	INVENTION	GAUZE	ALGINATES	FOAMS	HYDROCOLLOID	HYDROGELS	FILMS
REMOVE EXCESS EXUDATE	++	+	+	++	+	+	-
MAINTAIN MOIST WOUND HEALING ENVIRONMENT	+	+	+	+	+	+	++
ALLOW GASEOUS EXCHANGE	++	++	+	-	+	-	-
THERMAL INSULATION	++	+	+	++	+	+	+
AFFORD PROTECTION AGAINST SECONDARY INFECTION (SOURCES EXTERNAL TO BODY)	+	+	+	++	++	++	++
FREE FROM PARTICULATE (FIBERS, LINT)	+	--	--	+	+	+	+
SIMPLE ATRAUMATIC REMOVAL (LOW ADHERENCE TO WOUND)	+	-	-	+	-	-	-
HIGH ABSORPTION CAPACITY PER DRESSING	++	-	+	++	-	-	--
SLOW STRIKE THROUGH (WOUND EXUDATE ABSORBED THROUGH DRESSING)	++	-	--	++	++	++	++
ACCEPTABLE HANDLING CHARACTERISTICS							
-TEAR RESISTANT (UPON REMOVAL)	++	-	-	+	++	+	++
-DISINTEGRATION PROOF (WET AND DRY)	++	+	-	++	-	+	+
-CONFORMABILITY TO WOUND	++	+	+	+	-	+	-
-ABILITY TO PLACE UNDER WOUND EDGES	++	+	+	-	-	+	-
-ABILITY TO PLACE IN WOUND TRACTS	++	+	+	-	-	+	-
STERILIZABLE	+	+	+	+	+	+	+
INSTANTANEOUS WICKING	++	++	++	-	-	-	--
SUPPORTS AUTOLYSIS	++	-	+	-	-	-	+
SELECTIVE ATRAUMATIC DEBRIDEMENT	+	-	-	-	-	-	-
SOFT WOUND CONTACT SURFACE	+	-	-	+	+	+	+
COMPRESSIBLE	++	+	+	+	-	-	-
Key: + = demonstrate this property							
++ = strongly demonstrate this property							
- = poor performance							
-- = very poor performance							

Valentine Table 1 lists 20 properties or characteristics that Valentine posits as important in a wound dressing, for the uses discussed therein. Valentine asserts that the inventive dressing demonstrates, or strongly demonstrates, all 20 properties. In contrast, Valentine lists gauze as exhibiting poor or very poor performance in 8 of the 20 properties, and as performing worse than the inventive dressing in 11 of the 20 properties. Thus, it is clear from the comparison of Table 1 that Valentine does not regard gauze as an acceptable substitute for the disclosed dressing, and as such, Valentine unequivocally teaches away from the use of gauze. Valentine does not teach gauze as an alternate embodiment but instead teaches that gauze is a deficient prior art material.

Thus, a person of ordinary skill reading Valentine and Zamierowski would be motivated to avoid using gauze as a wound packing, and would have no expectation of successfully providing a wound packing having at least one predetermined direction of preferential contraction in response to suction by using gauze in a generally cylindrical roll having a generally longitudinal axis facing outwardly from the wound and radial axes facing sides of the wound, as recited in claim 25.

Second, contrary to the contention in the Office Action, Zamierowski does not teach or suggest that it would be desirable to have an intermediate material layer with greater absorbent capacity and smaller size. Therefore, there is no motivation to achieve such a goal, and thus no reasonable expectation of success by achieving such a goal. Moreover, Applicants' claimed purpose for using generally cylindrical rolls of gauze is to create an anisotropic wound packing that will allow preferential contraction in a predetermined direction, not to increase the absorbency and/or decrease the size of the gauze. *See* Specification at paragraphs [0005], [0010], and [0045] to [0047].

Further, the touted features of Valentine's dressing teach away from its use in suction wound therapy. A dressing for suction therapy allows fluid to be drawn therethrough by the suction and does not retain large amounts of fluid near the wound, which could result in bacterial infection. *See* Specification at paragraph [0008]. In contrast, Valentine teaches that the dressing is a sponge that absorbs the exudates from the wound and maintains an "optimal balance of fluid in contact with the wound surface." Valentine at col. 5, lines 59-61. In particular, Valentine discloses a wound dressing for use in certain types of wounds, the

dressings being “a cellular sponge . . . made of polyvinyl acetal,” which is disclosed as a very absorbent material holding up to 25 times its own weight in fluid. Valentine at col. 5, lines 48-55.

Therefore, the combination of Zamierowski and Valentine does not result in the claimed invention, and a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on these references or any other disclosure, teaching, or suggestion in the prior art. Accordingly, claim 25 is nonobvious over Zamierowski in view of Valentine.

Claim 26

Claim 26 depends from claims 23, 24, and 25, and therefore, without prejudice to its individual merits, claim 26 is patentable for at least the same reasons as claims 23, 24, and 25.

Claim 27

Claim 27 depends from claims 23 and 24, and therefore, without prejudice to its individual merits, claim 27 is patentable for at least the same reasons as claims 23 and 24.

Claim 39

In rejecting claim 39, the Office Action incorrectly determines the scope and content of the prior art, the initial first step in the *Graham* test for obviousness. First, the Office Action contends that Zamierowski teaches a method of controlling the direction of contraction of a wound. Second, the Office Action contends that Zamierowski teaches a step of placing a wound packing in a wound in a predetermined orientation. Third, the Office Action contends that gauze is a known packing material (citing Valentine) “which is anisotropic by nature.” None of these contentions are substantiated by the references themselves or by the knowledge of a person of ordinary skill in the art.

With regard to the first two contentions, Zamierowski does not teach controlling the direction of contraction of a wound or placing a wound packing in a wound in a medically preferred direction. Zamierowski merely places a dressing on top of a wound in no particular orientation and removes exudates from the dressing. There is no disclosure, teaching, or

suggestion in Zamierowski that the direction of healing wound is preferentially controlled in any direction.

With regard to the third contention, claim 39 does not recite gauze. Rather claim 39 recites that the dressing preferentially allows strain to be imposed on the wound tissue in a medically preferred direction. A flat sheet of dressing material placed on a wound, as taught by Zamierowski, is incapable of imposing strain on a wound in a particular direction. Moreover, the material taught by Valentine is polyvinyl acetal (i.e., foam) which is isotropic because it has the same properties in all directions, and therefore is also incapable of imposing strain on the wound tissue in a particular direction, much less in a medically preferred direction.

In sum, the combination of Zamierowski and Valentine does not result in the claimed invention, and a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on these references or any other disclosure, teaching, or suggestion in the prior art. Accordingly, claim 39 is nonobvious over Zamierowski in view of Valentine.

Accordingly, for at least the foregoing reasons, Applicants respectfully request that the obviousness rejections of claims 25, 26, 27, and 39 under Zamierowski in view of Valentine be withdrawn.

35 U.S.C. § 103 Rejection (Zamierowski in view of Valentine further in view of McNeil)

Claim 29 stands rejected under 35 U.S.C. § 103 as being obvious under Zamierowski in view of Valentine further in view of U.S. Patent No. 4,551,141 (McNeil).

As discussed above, Zamierowski fails to disclose the features of claims 23 and 28, from which claim 29 depends. Neither Valentine nor McNeil overcomes those deficiencies.

With specific regard to claim 29, the Office Action asserts that McNeil teaches that springs are an equivalent means of generating suction to bellows and bulbs in portable drainage devices, which could therefore be combined with Zamierowski. However, the rejection does not meet the claim, which recites a “spring element inside the bulb.”

Applicants have not replaced the bulb with a spring, as would be suggested by McNeil, but have supplemented the bulb with a spring element. As such, the bulb/spring combination has “resistance to rapid decay of suction in the bulb,” as claimed, which cannot be achieved merely by replacing the bulb with a spring. Because McNeil teaches interchangeability between a bulb and a spring, and not combination of a bulb and a spring, McNeil does not disclose the recited feature, and McNeil’s substitution cannot achieve the recited function.

Therefore, the combination of Zamierowski, Valentine, and McNeil does not result in the claimed invention, and a person of ordinary skill in the pertinent art at the time of the invention would not have reasonably expected to arrive at the claimed invention based on these references or any other disclosure, teaching, or suggestion in the prior art.

Accordingly, claim 29 is nonobvious over Zamierowski in view of Valentine further in view of McNeil. Additionally, claim 29 depends from claims 23 and 28, so without prejudice to its individual merits, claim 29 is patentable for at least the same reasons as claims 23 and 28. Thus, Applicants respectfully request that the obviousness rejection of claim 29 under Zamierowski in view of Valentine further in view of McNeil be withdrawn.

CONCLUSION

Accordingly, in view of the foregoing amendments and remarks, it is respectfully submitted that the application, including claims 23-29 and 39, is in condition for allowance. An early notice of allowance is earnestly solicited.

Respectfully submitted,

John R. BOEHRINGER et al.

CUSTOMER NUMBER:

23973

By:



Larry S. Zelson, Esq.

Registration No. 48,553

Drinker Biddle & Reath LLP

One Logan Square

18th & Cherry Streets

Philadelphia, PA 19103-6696

215-988-2932

215-988-2757 (fax)

Attorney for Applicants

Dated:

